PACKAGE LEAFLET: INFORMATION FOR THE USER
Lignospan Special 20 mg/ml + 12.5 micrograms/ml, solution for injection

Lidocaine hydrochloride and adrenaline

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your dentist, doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours
- If you get any side effects, talk to your dentist, doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:
1. What Lignospan Special is and what it is used for
2. What you need to know before you use Lignospan Special
3. How to use Lignospan Special
4. Possible side effects
5. How to store Lignospan Special
6. Contents of the pack and other information

1. What Lignospan Special is and what it is used for
Lignospan Special is given by injection to cause loss of feeling before and during dental procedures.
It contains two active ingredients:
- lidocaine hydrochloride, a local anaesthetic, which prevents pain,
- adrenaline tartrate, a vasoconstrictor which makes the effect last longer. Adrenaline narrows the blood vessels at the site of injection, which keeps the anaesthetic where needed for a longer time. It also controls the bleeding during the surgery.

Lignospan Special is for adults, children and adolescents.

Only a dentist can administer this product.

2. What you need to know before you use Lignospan Special

Do not use Lignospan Special
- if you are allergic to lidocaine hydrochloride or adrenaline tartrate or to any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to local anaesthetics called amide type anaesthetics,

Due to the presence of lidocaine, do not use this medicine:
- if you suffer from severe heart rhythm disorders (e.g. second and third AV block);
- if you suffer from a condition called *Porphyria* which causes either neurological complications or skins problems;

Due to the presence of adrenaline tartrate (adrenaline), a vasoconstrictor, do not use this medicine:
- if you have very high blood pressure (hypertension),
- if you have fast irregular heartbeat (tachyarrhythmia);
- if you have a tumour called *pheochromocytoma.*

Warning and precautions
Talk to your dentist before using Lignospan Special:
- if you have problems with your blood vessels (e.g. narrowing and hardening of the arteries that supply the legs and feet);
- if you have irregular heartbeat (arrhythmia);
- if you have heart failure;
- if you have low pressure (hypotension);
- if you suffer from a disease called *Myasthenia Gravis* causing weakness in the muscles;
- if you are epileptic;
- if you have problems with your liver;
- if you have problems with your kidney;
- if your thyroid is severely overfunctioning (thyrotoxicosis)
- if you have severe heart failure (ischemic heart or blood vessels/heart valves disease)
- if you receive a treatment with antiplatelets / anticoagulants;
- if you suffer from uncontrolled diabetes;
- if you suffer from a disease called acute angle-closure glaucoma which affects your eyes;
- if you are under the influence of illicit drug;
- if you are more than 70 years old;
- if you have inflammation or infection in the area to be injected;
- if you are allergic to sulfites.

Children
Lignospan Special is indicated in children. Special care has to be exercised when treating children below 4 years.

Other medicines and Lignospan Special
Please tell your dentist if you are taking, have recently taken or might take any other medicines. This is especially important if you are taking the following medicines, as precautions should be taken by your dentist:
- Other local anaesthetics;
- Opioid sedatives, used to relieve pain;
- Inhibitors of metabolism, used to treat heartburn and peptic ulcers;
- Heart and blood pressure medicines (for example guanadrel, guanethidine and beta blockers like propranolol and nadolol);
- Some anaesthetics that are inhaled (such as halotane);
- Tricyclic antidepressants used to treat depression (such as amitriptyline, desipramine, imipramine, nortriptyline, maprotiline and protriptyline);
- MAO inhibitors used to treat depressive or anxiety disorders (such as brofaromine, moclobemide, toloxatone, phenelzine, tranylcypromine);
- COMT inhibitors used to treat Parkinson's disease (such as entacapone or tolcapone);

- Drugs with combination of adrenergic-serotoninergic effect, used to treat depression, obsessive-compulsive disorders and anxiety (such as venlafaxine, milnacipran, sertraline);
- Medicines used to treat irregular heartbeats (for example digitalis, quinidine);
- Medicines used for migraine attacks (such as methysergide or ergotamine);
- Sympathomimetic vasopressors such as oxymetazoline used to treat swelling or inflammation of the nose;
- Other sympathomimetics;
- Neuroleptic drugs (for example phenothiazines);

If sympathomimetic vasopressor such as cocaine, amphetamines, phenylephrine, pseudoephedrine, oxymetazoline have been used within the past 24 hours, the planned dental treatment should be postponed.

Lignospan Special with food
You should avoid chewing gum or eating until normal sensation is restored after using this medicine. Otherwise there is a risk that you will bite your lips, cheeks or tongue.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your dentist, doctor or pharmacist for advice before using this medicine.
This medicine can be used during pregnancy and breastfeeding without any risk to the foetus or the breastfed child provided that it is taken as prescribed.

No effects on fertility were observed in preclinical studies.

Driving and using machines
Lidocaine in combination with adrenaline may have minor influence on the ability to drive and use machines. Dizziness (including vertigo, vision disorder and fatigue) may occur following administration of this product (see section 4. Side effects). Do not leave the dental office within 30 minutes following the dental procedure.

Lignospan Special contains sodium and potassium metabisulfite.
- Sodium (main component of cooking/table salt): 0.1132 mmol/ml (2.602 mg/ml). This is equivalent to approximately 0.665% of the recommended maximum daily dietary intake of sodium for an adult. The maximum recommended dose of this medicine (16 ml) contains 1.8112 mmol (41.632 mg) sodium, which is equivalent to 10.65% of the recommended maximum daily intake of sodium for an adult.
- Potassium metabisulfite: it may rarely cause severe allergic reactions and difficulty in breathing (bronchospasm). This medicine contains potassium less than 1 mmol (39 mg) for a maximal dose of 16 ml, i.e. essentially “potassium-free”.

3. How to use Lignospan Special
Only dentists and stomatologists are trained to use Lignospan Special, by a slow local injection.
Your dentist will adjust the dosage according to your age, your health and the dental procedure. The lowest dose leading to efficient anaesthesia should be used.
This medicine is given as an injection in the oral cavity.

Use in children

Special care has to be exercised when treating children below 4 years. The quantity to be injected should be determined by the age and weight of the child and the magnitude of the operation.

If you use more Lignospan Special than you should
If signs of acute systemic toxicity appear, administration should immediately be stopped and emergency medical assistance should be summoned.

If you have any further question on the use of this medicine, ask your dentist.

4. Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.

<u>Immediately</u> inform your dentist, doctor or pharmacist if you experience one of the following serious side effects:
- Rash, itching, swelling of the face and/or throat and difficulty breathing: this might be symptoms of an allergic / anaphylactic reaction;
- Loss of consciousness,
- Convulsion;
- Vision loss;
- Failure of the heart to contract effectively (cardiac arrest), rapid and erratic heartbeats (ventricular fibrillation);
- Abnormally slow breathing (respiratory depression), stopping breathing (apnoea);
- Painful and/or darkening tooth possibly with gum boil, which are the signs that the pulp tissue inside your tooth is dying.

Other side effects not listed above may also occur:

Common side effects (may affect up to 1 in 10 people):
- Pain due to nerve damage (neuropathic pain);
- Headache;
- Dizziness (lightheadedness);
- Tremor;
- Palpitations;
- Abnormal rapid heartbeat (tachycardia);
- Low blood pressure (hypotension), high blood pressure (hypertension);
- Pallor;
- Shortness of breath (dyspnoea);
- Pain, bruise at the injection site.

Uncommon side effects (may affect up to 1 in 100 people):
- Nausea, vomiting;
- Rash, itching (pruritus);
- Muscle pain (myalgia); joint pain (arthralgia).

Rare side effects (may affect up to 1 in 1,000 people):
- Difficulty in breathing, wheezing (bronchospasm, asthma);
- Hives (urticarial);
- Confusional state;
- Drowsiness;
- Vision blurred, problems clearly focusing an object, visual impairment.

Very rare side effects (may affect up to 1 in 10,000 people):
- Euphoric mood;
- Anxiety, nervousness, agitation, restlessness;
- Ringing in the ears (tinnitus);
- Heartbeat coordination problems (conduction disorders, atrioventricular block);
- Widening or narrowing of blood vessels;
- Hot flush;
- Excessive sweating (hyperhidrosis);
- Injection site pain.

Not Known (frequency cannot be estimated from the available data):
- Sloughing and ulceration of the gums;
- Difficulty in swallowing;
- Inflammation of the mouth and lips with canker sores (recurrent aphthous stomatitis), tongue (glossitis), or gum (gingivitis);
- Diarrhea;
- Swelling at the injection site;
- Malaise;
- Abnormal elevation of body temperature (pyrexia).

Additional side effects in children and adolescents
The safety profile was similar in children and adolescents from 4 to 18 years old compared to adults.

Reporting of side effects
If you get any side effects, talk to your dentist, doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lignospan Special

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the cartridge label and carton after EXP. The expiry date refers to the last day of that month.
Store below 25°C.
Keep the cartridge in the outer carton tightly closed, in order to protect from light.
Do not freeze.
Do not use this medicine if you notice that the solution is not clear and colourless.
The cartridges are for single use. If only a portion of a cartridge is used, the remainder must be discarded.
Do not throw away any medicines via wastewater or household waste. Ask your dentist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Lignospan Special contains

- The active substances are lidocaine hydrochloride 20 mg/ml and adrenaline tartrate expressed as base 12.5 micrograms/ml.
  One cartridge of 1.8 ml of solution for injection contains 36 mg of lidocaine hydrochloride and 22.5 micrograms of adrenaline (as tartrate).
  One cartridge of 2.2 ml of solution for injection contains 44 mg of lidocaine hydrochloride and 27.5 micrograms of adrenaline (as tartrate).

- The other ingredients are: potassium metabisulfite (E224), sodium chloride, disodium edetate, sodium hydroxide solution and water for injection.

What Lignospan Special looks like and content of the pack
This medicine is a solution for injection.
It is clear and colourless solution.
It is a packed in glass cartridges, sealed at one end by seal kept in place by a metal cap and at the other end by a mobile plunger.

The marketed presentation is cartridges of 1.8 ml or 2.2 ml contained in box of 50 cartridges.

Marketing Authorisation Holder and Manufacturer
For any information about this medicine, please contact the Marketing Authorisation Holder:

Marketing authorisation holder
Septodont Ltd, Units R & S
Orchard Business Centre
St Barnabas Close
Allington, Maidstone
Kent ME16 0JZ - UK

Manufacturer
Septodont
58, rue du Pont de Créteil
94100 Saint-Maur-des-Fossés
France

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The following information is intended for healthcare professionals only:

Posology and method of administration

Posology

As with any anaesthetic, doses vary and depend on the area to be anaesthetised, on the vascularity of tissues, on the number of nerve segments to be blocked, on the individual tolerance (degree of muscular relaxation and condition of the patient) and on the technique and depth of anaesthesia. The lowest dose leading to efficient anaesthesia should be used. The necessary dosage must be determined on an individual basis.

- Adults:

The maximum recommended dose is 7 mg/kg of body weight for a healthy adult above 50 kg of body weight with an absolute maximum dose of 500 mg of lidocaine or 200 micrograms of adrenaline. However, due to this product's fixed component of adrenaline 1:80,000, the latter will determine the maximum administered quantity to be 16 ml solution (containing 200 micrograms of adrenaline) which must not be exceeded.

			Equivalent in cartridges numbers	
Lidocaine dose (mg)	Adrenaline dose (mg)	Volume (ml)	1.8 ml	2.2 ml
320	0.200	16	8.9	7.3

- Adolescents (12 to 18 years of age) and children (4 to 11 years of age)

Special care has to be exercised when treating children below 4 years. The quantity to be injected should be determined by the age and weight of the child and the magnitude of the operation. The anaesthesia technique should be selected carefully. Painful anaesthesia techniques should be avoided. The behaviour of the child during treatment has to be monitored carefully.

The average dose to be used is in the range of 20 mg to 30 mg lidocaine hydrochloride per session. The dose in mg of lidocaine hydrochloride which can be administered in children may alternatively be calculated from the expression: child's weight (in kilograms) x 1.33.

Do not exceed the equivalent of 5 mg of lidocaine hydrochloride per kilogram of body weight. The number of cartridges corresponding to the maximum dose of 5 mg/kg can be calculated as follows:

Patient weight (kg) x Maximum lidocaine dose (mg/kg) / Quantity of lidocaine per cartridge (mg)

				Equivalent in cartridges numbers	
Weight (kg)	Lidocaine dose (mg)	Adrenaline dose (mg)	Volume (ml)	1.8 ml	2.2 ml
20	100	0.0625	5	2.8	2.3
30	150	0.09375	7.5	4.2	3.4
40	200	0.125	10	5.6	4.5
50	250	0.15625	12.5	6.9	5.7

- Special populations

Due to the lack of clinical data, particular precaution should be used in order to administer the lowest dose leading to effective anaesthesia in elderly patients over 70 years old and in patients with renal or hepatic impairment.

Method of administration:
Infiltration or nerve block injection.
Before injection, aspiration should always be performed to avoid intravascular injection and if required, the needle repositioned until no return of blood can be elicited by aspiration. The absence of blood in the syringe does not guarantee that intravascular injection has been avoided.
Major systemic reactions as a result of accidental intravascular injection can be avoided in most cases by an injection technique after aspiration with a slow injection: the rate of injection should not exceed 1 ml of solution per minute.
To avoid risk of infection (e.g. hepatitis transmission), syringe and needles used to draw up the solution must always be fresh and sterile.
For single use. Any unused solution should be discarded.
The medicinal product should not be used if cloudy or discoloured.
For information relevant to the handling of the product, see section 6.6. of the SmPC.

Special warning and precautions

Risk associated with an accidental intravascular injection:
Accidental intravascular injection (e.g.: inadvertent intravenous injection into the systemic circulation, inadvertent intravenous or intra-arterial injection in the head area and neck area) may be associated with severe adverse reactions, e.g., convulsions, followed by central nervous system or cardiorespiratory depression and coma, progressing ultimately to respiratory arrest, due to the sudden high level of adrenaline and / or lidocaine in the systemic circulation.

Risk associated with intraneural injection:
Accidental intraneural injection may lead the drug to move in retrograde manner along the nerve.
In order to avoid intraneural injection and to prevent nerve injuries in connection with nerve blockades, the needle should always be slightly withdrawn if electric shock sensation is felt by the patient during injection or if the injection is particularly painful. If needle nerve injuries occur, the neurotoxic effect could be aggravated by lidocaine's potential chemical neurotoxicity and the presence of adrenaline as it may impair the perineural blood supply and prevent lidocaine local wash-out.

Risk of Takotsubo cardiomyopathy or stress-induced cardiomyopathy:
Stress cardiomyopathy induced by injected catecholamines has been reported.
Because of the presence of adrenaline, precautions and monitoring should be enhanced in the following situations: patients stressed prior to dental procedure or conditions of use which may contribute to induce a systemic passage of adrenaline e.g. an administered dose higher than recommended or in case of an accidental intravascular injection.
Any previous knowledge of such underlying conditions in patients requiring dental anaesthesia should be minded and a minimal dose of local anaesthetic with vasoconstrictor used.

Concomitant use of the other medicinal products may require thorough monitoring (see section 2 - Other medicines of this leaflet or section 4.5- Interactions of the SmPC).

Overdose

Types of overdose
Local anaesthetic overdose in the largest sense is often used to describe:
- Absolute overdose
- Relative overdose

- inadvertent injection into a blood vessel, or
- abnormal rapid absorption into the systemic circulation, or
- delayed metabolism and elimination of the product.

Symptomatology

- Due to lidocaine:

The symptoms are dose-dependent and have progressive severity in the realm of neurological manifestations, followed by vascular, respiratory, and finally cardiac toxicity (detailed in section 4.8).

- Due to adrenaline:

Overdose of adrenaline may cause cardiovascular effects.

Treatment of overdose

The availability of resuscitation equipment should be ensured before the onset of dental anaesthesia with local anaesthetics.
If signs of acute toxicity are suspected, the injection of this product must immediately be stopped.
Oxygen should rapidly be administered, if necessary by assisted ventilation. Change patient position to supine position if necessary.
In case of cardiac arrest, immediate initiation of cardiopulmonary resuscitation is necessary.

Special precautions for disposal

One cartridge can only be used for one single patient during one single session.
No opened cartridge of anaesthetic solution should be reused. If only a part is used, the remainder must be discarded.
Any unused product or waste material should be disposed of in accordance with local requirements.